



Effect of Emulgel containing Langkasuka Oil versus Diclofenac Gel for Improving Physical Function in Patients with Knee Osteoarthritis: A randomized controlled trial

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Abstract

Knee osteoarthritis (KOA) is characterized by a progressive decline in physical functioning. Emulgel containing Langkasuka oil (ELO) represents a newly developed formulation incorporating Langkasuka oil (LO) as an active constituent. This study aimed to evaluate the impact of ELO on lower limb function and mobility, as assessed by the Timed Up and Go (TUG) test and 30-Second Chair Stand (30-CST) test. A randomized controlled trial was performed between July 2025 and February 2026. A total of 62 participants were randomly allocated into two groups of 31 each: an experimental group receiving topical ELO and a control group receiving topical diclofenac gel (DG). Both groups were instructed to apply the assigned substance to the knee area three times daily for a period of four weeks. Outcome measures were assessed at baseline, day 14, and day 28. Statistical analysis was performed using repeated measures ANOVA to assess within-group changes over time, and one-way ANOVA to examine between-group differences. The results of the ELO group showed a progressive decline in mean scores from 11.29 ± 1.42 at baseline to 8.10 ± 0.94 at Day 28, indicating a clinically significant transition from moderate fall risk to normal functional status. A comparable reduction was observed in the DG group, with mean scores decreasing from 11.26 ± 1.55 at baseline to 8.06 ± 1.12 at Day 28. Both the ELO and DG groups demonstrated statistically significant improvements in 30-CST performance over the 28-day intervention period ($p < 0.001$), with mean scores increasing from 8.61 ± 1.05 to 10.26 ± 1.29 and from 8.65 ± 0.98 to 10.13 ± 1.26 , respectively. In conclusion, ELO demonstrated physical performance improvements comparable to those observed with DG, suggesting its potential as an alternative topical therapeutic option for the management of KOA.

Keywords: Knee osteoarthritis, Emulgel, Langkasuka Oil, Physical function, Diclofenac gel

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1. Introduction

Knee osteoarthritis (KOA) ranks among the most prevalent musculoskeletal conditions worldwide and has been the most extensively investigated joint disorder with respect to disease frequency [1]. Prevalence estimates vary considerably across geographic

regions, with approximately 17% of adults aged ≥ 45 years affected in the United States [2], 14.6% in China [3], and 4.0–59.4% among Thai adults aged ≥ 45 years, with variability attributed to differences in diagnostic criteria and study populations [4]. Well-established risk factors include advancing age, female sex, obesity, prior knee injury, family history of

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osteoarthritis, and occupational physical loading [5]. Disease progression in KOA is characterized by chronic pain, progressive impairment of physical function, and reduced participation in occupational, social, and recreational activities, collectively contributing to diminished health-related quality of life [7]. Current evidence-based management guidelines for KOA prioritize three therapeutic objectives: pain alleviation, restoration of physical function, and attenuation of disease progression. Among pharmacological strategies, nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as the cornerstone of first-line treatment [6]. Topical diclofenac gel exerts its therapeutic effects by penetrating the skin and diffusing into deeper periarticular tissues, including the synovial membrane, thereby enabling direct pharmacological action at the site of pain and inflammation. Its principal mechanism of action involves selective inhibition of cyclooxygenase-2 (COX-2), reflected by a COX-1/COX-2 IC₅₀ ratio of 29 [8], which suppresses the conversion of arachidonic acid into pro-inflammatory prostaglandins and attenuates local inflammatory activity at the affected joint [9,10]. Despite being a recommended first-line therapeutic option for KOA, topical nonsteroidal anti-inflammatory drugs (NSAIDs) are not without limitations, as their use has been associated with localized cutaneous reactions and transient mild adverse effects [11]. There is therefore a compelling need to explore plant-derived products as alternative therapeutic options for the management of KOA.

Langkasuka Oil (LO) is a traditional herbal massage oil composed of a blend of medicinal plant extracts, formulated by integrating the traditional healing knowledge of local midwives (Tok Bidae) with Thai massage principles [12]. LO comprises nine medicinal plants: *Tacca leotopetaloides*, *Zingiber montanum*, *Curcuma longa*, *Pandanus amaryllifolius*, *Salacia chinensis*, *Citrus hystrix*, *Cymbopogon citratus*, *Nigella sativa*,

and *Piper nigrum* [13]. The predominant component, Phlai (*Zingiber montanum*) rhizome, contains diverse secondary metabolites including phenylbutenoids and their dimers which exhibit significant anti-inflammatory properties [14]. Chemical analysis of coconut oil-fried Phlai further identified compound-D and related cassumunoids with notable anti-inflammatory activity in animal models, with a minimum effective concentration of 25% required for therapeutic efficacy [15]. Turmeric (*Curcuma longa*), another key constituent, contains curcumin a lipophilic polyphenol with well-documented antioxidant, anti-inflammatory, and antineoplastic activities relevant to cancer, autoimmune, neurological, cardiovascular, and metabolic conditions [16]. It has been used therapeutically to relieve musculoskeletal pain, improve muscle function, and enhance blood circulation, with particular benefits for elderly patients with knee pain and no reported contraindications [13]. A clinical study demonstrated that self-massage using LO applied bilaterally to the neck and shoulder muscles over 7 days significantly reduced pain intensity and improved cervical range of motion in all six directions among patients with office syndrome [17]. Based on the systematic review by Dobson et al. [18], the Timed Up and Go (TUG) test and the 30-second chair stand test have been established as the most well-supported performance-based measures for assessing physical function in individuals with hip and knee OA, underscoring their value as reliable and clinically relevant tools for functional evaluation in this patient population. However, studies examining the impact of ELO on physical function among patients with OAK are limited. this study aimed to evaluate its impact on lower limb function and mobility, as measured by the TUG test and 30-CST test. It was hypothesized that ELO intervention would result in comparable improvements in both outcomes relative to the DG group.

2. Methodology

2.1 Research design

This study was approved by the Human Research Ethics Committee of Phetchaburi Rajabhat University, it was conducted in accordance with the Helsinki Declaration no. 11/2025. The study was carried out at a subdistrict health promotion hospital in Amphoe Mueang from July 2025 to February 2026. Participant allocation was conducted via a randomized complete block design (RCBD), stratified by knee pain severity. A double-blind procedure was implemented, ensuring that neither the participants nor the investigators had knowledge of group assignments during the study. The diclofenac gel (DG) container was modified to match the green color of ELO, rendering the two preparations visually indistinguishable and thereby maintaining the integrity of the double-blind study design.

2.2 Drug preparation

The LO extraction was conducted in two sequential steps. The first step involved heating *T. leontopetaloides*, *C. citratus*, and *C. hystrix* peel in palm oil, followed by filtration. The second step began with heating *Z. montanum* and *C. longa* in palm oil in Traditional clay pot container over low heat. This base was then enriched with *S. chinensis*, *T. leontopetaloides*, *C. citratus*, *C. hystrix* peel, *P. amaryllifolius* leaves, and powdered *N. sativa* and *Piper nigrum*. After 6-12 hours of gentle simmering, the mixture was allowed to cool overnight for complete infusion. Subsequently, medicated oil, dissolved camphor-menthol mixture, and massage oil were added to the preparation and heated until thoroughly combined [13]. The ELO was prepared at the Faculty of Integrative Medicine, Rajamangala University of Technology Thanyaburi.

2.3 Sample size and patient's characteristic

Sample size was calculated using G*Power version 3.1.9.4, based on an effect size of 0.80 derived from pain intensity variance reported in a previous study of similar

design [19], with a significance level of 0.05 and a power of 0.90. An additional 10% was added to account for anticipated dropout, resulting in a required sample of 31 participants per group. Eligible participants included both males and females aged 50–80 years, with a primary knee osteoarthritis diagnosis confirmed by an orthopedic physician in accordance with the American College of Rheumatology clinical criteria and Kellgren-Lawrence radiographic grading of 1–3. Participants were excluded if they presented with any of the following: open knee wounds, planned knee arthroplasty within three months, known allergy to herbal preparations or alcohol, pregnancy or lactation, gout, pseudogout, rheumatoid arthritis, recent knee injury, paralysis, or Parkinson's disease. Additional exclusion criteria encompassed concurrent use of topical medications on the knee, use of NSAIDs or other knee osteoarthritis-related treatments including physiotherapy, knee massage, or acupuncture within the preceding 7 days, intra-articular injection of corticosteroid or hyaluronate within the past 3 months, use drugs such as glucosamine, diacerein, or chondroitin within the past 4 months. Should no allergic reaction be observed, the investigator provided a structured demonstration of the correct application method, after which participants were guided through hands-on practice as outlined in the research manual. Following baseline assessment of pain intensity using the Visual Analogue Scale (VAS) and physical function parameters, participants were assigned to either the experimental group, which applied Langkasuka Oil emulgel, or the control group, which applied diclofenac gel. Both groups received standardized training on proper product application and were instructed to apply the assigned intervention to the knee area three times daily morning, noon, and evening for four consecutive weeks. Compliance and symptom monitoring were facilitated through a daily self-reported diary maintained by each participant throughout the study period.

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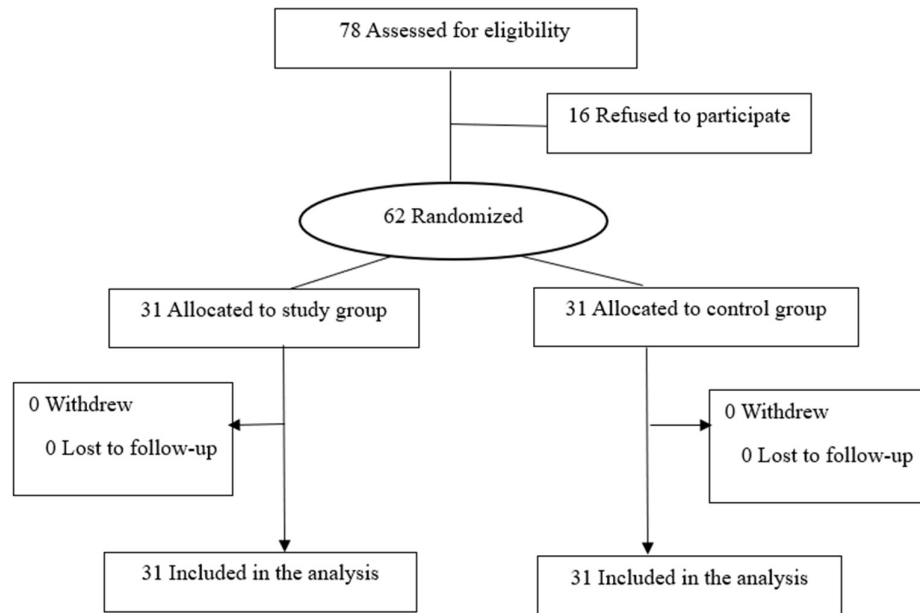


Figure 1. Flowchart of study

2.4 Outcome measurement

The TUG test was utilized to evaluate functional mobility and fall risk in all participants, with assessments consistently performed using a standardized chair with armrests. Each participant was instructed to rise from the seated position, with armrest assistance permissible if required, walk toward a line placed 3 meters away, turn, and return to sit in the chair. The recorded time began when the participant's buttocks lifted from the chair and ended upon their return to the seated position [20]. The 30-CST was conducted on a standardized armless folding chair with a seat height of 43.2 cm (17 inches). Participants were seated upright, with feet flat on the floor

at shoulder-width apart and arms crossed at the wrists against the chest. One to two practice trials were provided prior to formal testing, and any participant requiring arm support to stand was assigned a score of zero. Upon the start signal, participants alternated between a fully erect standing position and complete seated contact with the chair, aiming to complete the maximum number of stand-to-sit cycles within 30 seconds. The total number of fully completed stands constituted the final score [21].

2.5 Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics version 24.0 (IBM

Co., Armonk, NY, USA). In this study [22], within-group differences across successive time points were analyzed using repeated measures ANOVA, while between-group comparisons were performed using one-way ANOVA. Statistical significance was defined as a *p*-value of less than 0.05.

3. Results and Discussion

Sixty-two participants were enrolled and equally randomized into two groups, all of whom successfully completed the study as shown in Figure 1. The sample was predominantly female, representing 80% of the total population, with a mean age of 62 years and above. Mean BMI values ranged between 25 -26 kg/m², placing the majority of participants within the overweight classification.

Table 1. Physical function parameters within and between groups cut off at baseline, day 14 and day 28.

Measure	Baseline (mean±SD)	Day14 (mean±SD)	Day28 (mean±SD)	^a <i>p</i> -value
TUG				
ELO group	11.29±1.42	9.61±1.05	8.10±0.94	<0.001*
DG group	11.26±1.55	9.65±1.28	8.06±1.12	<0.001*
^b <i>p</i> -value	0.932	0.914	0.903	
30-CST				
ELO group	8.61±1.05	9.32±1.08	10.26±1.29	<0.001*
DG group	8.65±0.98	9.35±1.11	10.13±1.26	<0.001*
^b <i>p</i> -value	0.901	0.908	0.692	

^a*p*-value is calculated by repeated measure ANOVA test to determine differences within groups in different periods.

^b*p*-value is calculated by ANOVA for comparison between group.

**p*<0.001: statistically significant differences.

The TUG test measures mobility and dynamic balance, whereby a reduced completion time indicates superior physical dexterity and functional ability [23]. The threshold values used to assess fall risk have varied considerably across the literature, with older studies reporting a range of 10 to 33 seconds [24], whereas more recent investigations suggest a narrower range of 8.1 to 16 seconds [25]. Results are interpreted as follows: completing the test in 10 seconds or under is regarded as normal, a completion time ranging from 11 to 20 seconds reflects a moderate fall risk, while a time of more than 20 seconds is indicative of a high risk of falling [26]. In both groups, TUG parameters showed statistically significant reductions following 28 days of intervention (*p*<0.001) (Table 1). In the ELO group, mean scores declined from 11.29±1.42 at baseline to 8.10±0.94 at Day 28, representing a shift from

moderate fall risk to normal. Similarly, the DG group demonstrated a reduction from 11.26±1.55 at baseline to 8.06±1.12 at Day 28, also transitioning from moderate fall risk to the normal range. These results indicate that both treatments successfully enhanced mobility and lowered the risk of falling among study participants, which is in line with previously reported evidence on the use of Ya pok Dud pid, where a decline in TUG scores to 8.20±1.22 was observed at the 42-day follow-up assessment [27].

The 30 CST was applied as an assessment of lower limb muscle strength, capturing the number of chair stand repetitions an individual could complete within a 30-second interval [28]. For individuals aged below 80 years, a score of approximately 10 points is considered within the normal range [26]. Both the ELO and DG groups exhibited statistically significant improvements in 30

CST performance following 28 days of intervention ($p < 0.001$), with mean scores rising from 8.61 ± 1.05 to 10.26 ± 1.29 and from 8.65 ± 0.98 to 10.13 ± 1.26 , respectively. Notably, participants in both groups progressed from below-normal values at baseline to within the normal range of approximately 10 repetitions by the end of the study period, highlighting the equivalent effectiveness of both treatments in enhancing lower limb muscle strength among the study participants.

The improvement in physical function observed among patients with knee osteoarthritis may be attributable to the bioactive constituents of ELO, particularly *Nigella sativa*, which serves as a principal component of the formulation. Thymoquinone, considered one of the primary active constituents of *N. sativa* extract, has been shown to possess analgesic properties, making it a potentially valuable agent in the management of pain and inflammatory conditions [29]. Furthermore, previous research has demonstrated that topical administration of *N. sativa* oil over a 21-day treatment period produced greater analgesic benefits in of life in patients with upper trapezius myofascial pain syndrome comparison to diclofenac gel [30]. Phlai, a key constituent of ELO, has been reported to alleviate pain, improve range of motion, and enhance quality of life [31].

KOA related activity limitations have been shown to impair social participation and mental health outcomes, thereby leading to a marked reduction in the overall quality of life (QoL) experienced by affected individuals [32]. QoL can be measured using two principal approaches: 1) a generic instrument that captures the broad influence of disease on a patient's overall health status, 2) a disease-specific instrument that exclusively assesses the effect of the condition on those QoL domains most directly implicated by the disease itself. An increasing number of studies have suggested that the deterioration of QoL observed in individuals with knee osteoarthritis may result directly from diminished physical

mobility, worsening pain experience, imbalanced musculature, and an overall reduction in functional capacity [33]. A study conducted among older adults with knee osteoarthritis in India demonstrated consistently poor scores across all physical health-related quality of life domains, including physical functioning (PF), role limitation attributable to physical health (RP), bodily pain (BP), energy and vitality (VT), general health perception (GH), and perceived health transition [34]. Similarly, the researcher reported statistically significant impairment across all QoL subscales, with the exception of the role emotional and general health (GH) domains [35].

There were several limitations to this study. First, physical health-related quality of life domains were not assessed, which may have limited a comprehensive evaluation of the intervention's overall impact on patient well-being. Second, the follow-up duration was restricted to 28 days, which may be insufficient to capture long-term therapeutic effects; future studies should incorporate extended follow-up periods. Third, the study sample consisted predominantly of female participants, which may limit the generalizability of the findings to the broader KOA population. Future studies should investigate larger sample sizes.

4. Conclusion and Recommendations

The present study demonstrates that both ELO and DG interventions produced significant improvements in mobility, dynamic balance, and lower limb muscle strength among patients with knee osteoarthritis over the 28-day treatment period. TUG and 30 CST scores in both groups transitioned from below-normal values at baseline to within the normal range at Day 28, reflecting clinically meaningful gains in functional performance and a substantial reduction in fall risk. The bioactive constituents of ELO, particularly *N. sativa* and Phlai, may have contributed to these therapeutic effects through their established analgesic and anti-

inflammatory properties. Notably, ELO demonstrated comparable efficacy to DG, suggesting its potential as an alternative topical intervention for the management of knee osteoarthritis. Nevertheless, these findings should be interpreted with caution, given the absence of a placebo control group. Future placebo-controlled trials are warranted to more rigorously establish the therapeutic efficacy of ELO in this patient population.

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